K063329

510(k) Summary

APR 16 2007

Abbott ARCHITECT® HAVAB®-M

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

According to the requirements of 21 CFR §807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter's Name & Address: Abbott Laboratories
Diagnostic Division
Department 09V6, Building AP6C-2
100 Abbott Park Road
Abbott Park, Il 60064-6187
Telephone: (847) 938-6141
Fax: (847) 937-9616
Contact: Joseph C. Orlowski

Date Prepared: November 2, 2006
Date Revised: April 13, 2007
Device Proprietary Name: ABBOTT ARCHITECT® HAVAB®-M
Device Common Name: IgM antibody to hepatitis A virus (IgM anti-HAV)
Classification Number: 21 CFR §866.3310

Predicate Device: ABBOTT AxSYM® HAVAB®-M 2.0 assay.
PMA Number: P790012/S011
Decision Date: February 2, 2004
Device reclassified from class III to class II
(Guidance Document February 9, 2006)

Device Description:
The ARCHITECT HAVAB-M assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgM antibody to hepatitis A virus (IgM anti-HAV) in human adult and pediatric serum and plasma and neonatal serum. The ARCHITECT HAVAB-M assay is calibrated with ARCHITECT HAVAB-M Calibrator. ARCHITECT HAVAB-M Controls are used for monitoring the performance of the Abbott ARCHITECT *i* System.

Device Intended Use:
ARCHITECT HAVAB-M assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgM antibody to hepatitis A virus (IgM anti-HAV) in human adult and pediatric serum and plasma (dipotassium EDTA, lithium heparin, and sodium heparin) and neonatal serum. A test for IgM anti-HAV is indicated for testing of specimens from individuals who have signs and symptoms consistent with acute hepatitis. Test results are used in conjunction with other laboratory results and clinical information as an aid in the diagnosis of acute or recent hepatitis A viral infection.
Warning: Not intended for use in screening blood, plasma, or tissue donors. The effectiveness of ARCHITECT HAVAB-M for use in screening blood, plasma, or tissue donors has not been established. Assay performance characteristics have not been established when the ARCHITECT HAVAB-M assay is used in conjunction with other manufacturers' assays for specific hepatitis markers. Users are responsible for establishing their own performance characteristics.

The Intended Use of Predicate Device:
AxSYM HAVAB-M 2.0 is a microparticle enzyme immunoassay (MEIA) for the qualitative detection of IgM antibody to hepatitis A virus (IgM anti-HAV) in human serum or plasma (potassium EDTA, sodium heparin, sodium citrate, or lithium heparin). A test for IgM anti-HAV is indicated as an aid in the laboratory diagnosis of acute or recent hepatitis A viral infection. Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with hepatitis A virus in persons with signs or symptoms of hepatitis and in persons at risk for hepatitis A infection. WARNING: Assay performance characteristics have not been established for testing a pediatric population less than 10 years of age.

Instrument Percent Agreement:
A study was conducted to confirm that the ARCHITECT HAVAB-M assay can be used on the ARCHITECT i 2000 and ARCHITECT i 2000SR systems. One hundred IgM anti-HAV negative specimens and 67 IgM anti-HAV positive specimens were tested on two instruments (one i 2000 and one i 2000SR) using two lots of reagents and one lot of calibrators and controls. One replicate of each specimen was tested with the same reagent lot on both instruments. The negative percent agreement was 100.0% with a 95% confidence interval of 96.38% to 100.00%, and the positive percent agreement was 100.0% with a 95% confidence interval of 94.64 to 100.00%.

Comparison of Results and Percent Agreement:
The positive percent agreement of the ARCHITECT HAVAB-M assay with the comparator assay for the prospectively collected population was 98.10%, with a 95% confidence interval of 93.29% to 99.77%. The negative percent agreement of the ARCHITECT HAVAB-M assay with the comparator assay for the prospectively collected population was 100.00%, with a 95% confidence interval of 99.34% to 100.00%.

The positive percent agreement of the ARCHITECT HAVAB-M assay with the comparator assay for the acute HAV population is 98.10%, with a 95% confidence interval of 93.29% to 99.77%.

The negative percent agreement of the ARCHITECT HAVAB-M assay with the comparator assay for a pediatric population at low risk for hepatitis is 100.00%, with a 95% confidence interval of 96.38% to 100.00%.

The positive percent agreement for a prospectively collected pediatric population is 98.88%, with a 95% confidence interval of 93.90% to 99.97% and the negative percent agreement is 100.00%, with a 95% confidence interval of 75.29% to 100.00%.

In conclusion, these data demonstrate that the ARCHITECT HAVAB-M assay is as safe and effective as, and is substantially equivalent to, the Abbott AxSYM HAVAB-M 2.0 assay.

Prepared by and Submitted by:
Joseph C. Orlowski, RAC
Senior Regulatory Affairs Administrator
ADD Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Joseph C. Orlowski, RAC
Sr. Regulatory Affairs Administrator
Abbott Laboratories
Diagnostic Division
100 Abbott Park Road
Department 09V6, Building AP6C-2
100 Abbott Park, IL 60064-6187

APR 16 2007

Re: k063329
Trade/Device Name: ARCHITECT® HAVAB®-M
ARCHITECT® HAVAB®-M Calibrator
ARCHITECT® HAVAB®-M Controls
Regulation Number: 21 CFR 866.3310
Regulation Name: Hepatitis A virus (HAV) serological assays
Regulatory Class: Class II
Product Code: LOL
Dated: March 22, 2007
Received: March 23, 2007

Dear Mr. Orlowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

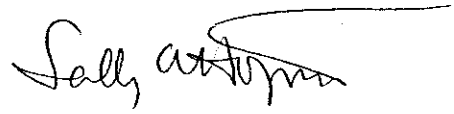
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k063329

Device Name: ARCHITECT® HAVAB®-M
ARCHITECT® HAVAB®-M Calibrator
ARCHITECT® HAVAB®-M Controls

Indications for Use:

The ARCHITECT HAVAB-M assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgM antibody to hepatitis A virus (IgM anti-HAV) in human adult and pediatric serum and plasma (dipotassium EDTA, lithium heparin, and sodium heparin) and neonatal serum. A test for IgM anti-HAV is indicated for testing of specimens from individuals who have signs and symptoms consistent with acute hepatitis. Test results are used in conjunction with other laboratory results and clinical information as an aid in the diagnosis of acute or recent hepatitis A viral infection.

Warning: Not intended for use in screening blood, plasma, or tissue donors. The effectiveness of ARCHITECT HAVAB-M for use in screening blood, plasma, or tissue donors has not been established.
Assay performance characteristics have not been established when the ARCHITECT HAVAB-M assay is used in conjunction with other manufacturers' assays for specific hepatitis markers. Users are responsible for establishing their own performance characteristics.

ARCHITECT HAVAB-M Calibrator:
The ARCHITECT HAVAB-M Calibrator is used to calibrate the ARCHITECT *i* System when the system is used for the qualitative detection of IgM antibody to hepatitis A virus (IgM anti-HAV) using the ARCHITECT HAVAB-M Reagent Kit. The performance of the ARCHITECT HAVAB-M Calibrator has not been established with any other IgM anti-HAV assays.

ARCHITECT HAVAB-M Controls:
The ARCHITECT HAVAB-M Controls are used for monitoring the performance of the ARCHITECT *i* System when used for the qualitative detection of IgM antibody to hepatitis A virus (IgM anti-HAV) using the ARCHITECT HAVAB-M Reagent Kit. The performance of the ARCHITECT HAVAB-M Controls has not been established with any other IgM anti-HAV assays.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K063329